

Codes in General: The notation '.' indicates value unknown.

The reason for not starting study treatment (reported in Figure 1 of the primary publication for this trial) is not provided within this data submission due to de-identification procedures.

Variable	Label	Code
study	ECOG-ACRIN (EA) Protocol Number	C0590
group_uid	A Blinded Patient ID Generated by EA	
arm	Assigned Treatment Arm	A=13-cisretinoic acid (13-CRA), B=placebo
age	Age at Study Entry (Years)	
region	Disease Site	1=oral cavity, 2=oropharynx, 4=larynx
sex	Sex	1=male, 2=female
stage	Disease Stage	1=stage I, 2=stage II, 3=stage III
priorthrpy	Prior Therapy	1=radiotherapy, 2=surgery, 3=combined
ps	ECOG Performance Status (Day 1)	
white	NCI Race	0=non-White, 1=White
smoke_bsln	Smoking History at Baseline	1=never smoked, 2=smoked previously, 3=current smoker
smoke_fu	Smoking Status at Follow-up	1=no smoking after baseline, 2=smoking after baseline
sptumor	Site of Second Malignancy	
offtxreason	Off Treatment Reason	1=treatment complete, 2=disease progression, 3=excess toxicity, 4=death, 5=patient withdrawal/refusal, 6=non-protocol therapy, 7=other complicating disease, 8=error, 10=other
tx_1yr	Treatment over 1 Year	0=no, 1=yes
tx_2yr	Treatment over 2 Years	0=no, 1=yes
cod	Cause of Death	1=due to protocol treatment, 2=due to this disease, 3=due to other cause
surtime	Overall Survival Time (Years)	
sta	Survival Censor Index	0=censor, 1=dead
status	Survival Status	1=alive, 2=dead, 3=lost to follow- up (LFU), 7=refused follow-up, 8=official LFU
sur2time	Time to 2nd Primary (Years)	
sta2_crr	Status for Time to Secondary Primary Event	0=censor, 1=event, 2=dead without event reported
dq08	Skin	dq08-dq23 refer to the degree of various 13 CRA toxicity. For all these variables, 0=grade 0, 1=grade 1, 2=grade 2, 3=grade 3, 4=grade 4.
dq09	Cheilitis	
dq10	Conjunctivitis	
dq11	Epistaxis	
dq12	Hair	
dq13	Nausea	
dq14	Diarrhea	
dq15	Neuro-Headache	
dq16	Reproductive Function	
dq17	Bladder	
dq18	Musculoskeletal	
dq19	Fatigue	
dq20	Liver	

Variable	Label	Code
dq21	Serum Cholesterol	
dq22	Serum Triglycerides	
dq23	HDL Cholesterol	
bk01	DEGREE LEUKOPENIA	bk01-bk79 contain toxicity data (per CTC). Toxicity degree: 0='none or normal', 1='mild', 2='moderate', 3='severe', 4='life-threatening', 5='lethal'. Toxicity rx-related: 1='yes, probably', 2='possibly', 3='definitely not'.
bk02	RX-RELATED LEUKOPENIA	
bk03	DEGREE THROMBOCYTOPENIA	
bk04	RX-RELATED THROMBOCYTOPEN	
bk05	DEGREE ANEMIA	
bk06	RX-RELATED ANEMIA	
bk07	DEGREE HEMORRHAGE	
bk08	RX-RELATED HEMORRHAGE	
bk09	DEGREE INFECTION	
bk10	RX-RELATED INFECTION	
bk11	DEGREE FEVER(NO INFECTION	
bk12	RX-RELATED FEVER(NO INFEC	
bk13	DEGREE GU	
bk14	RX-RELATED GU	
bk15	DEGREE NAUSEA	
bk16	RX-RELATED NAUSEA	
bk17	DEGREE VOMITING	
bk18	RX-RELATED VOMITING	
bk19	DEGREE DIARRHEA	
bk20	RX-RELATED DIARRHEA	
bk21	DEGREE STOMATITIS	
bk22	RX-RELATED STOMATITIS	
bk23	DEGREE LIVER	
bk24	RX-RELATED LIVER	
bk25	DEGREE PULMONARY	
bk26	RX-RELATED PULMONARY	
bk27	DEGREE CARDIAC	
bk28	RX-RELATED CARDIAC	
bk29	DEGREE HYPERTENSION	
bk30	RX-RELATED HYPERTENSION	
bk31	DEGREE HYPOTENSION	
bk32	RX-RELATED HYPOTENSION	
bk33	DEGREE SKIN	
bk34	RX-RELATED SKIN	
bk35	DEGREE ALLERGY	
bk36	RX-RELATED ALLERGY	
bk37	DEGREE PHLEBITIS	
bk38	RX-RELATED PHLEBITIS	
bk39	DEGREE LOCAL(NO PHLEBITIS	

Variable	Label	Code
bk40	RX-RELATED LOCAL(NO PHLEB	
bk41	DEGREE ALOPECIA	
bk42	RX-RELATED ALOPECIA	
bk43	DEGREE WEIGHT GAIN	
bk44	RX-RELATED WEIGHT GAIN	
bk45	DEGREE WEIGHT LOSS	
bk46	RX-RELATED WEIGHT LOSS	
bk47	DEGREE NEURO-SENSORY	
bk48	RX-RELATED NEURO-SENSORY	
bk49	DEGREE NEURO-MOTOR	
bk50	RX-RELATED NEURO-MOTOR	
bk51	DEGREE NEURO-PSYCH	
bk52	RX-RELATED NEURO-PSYCH	
bk53	DEGREE NEURO-CLINICAL	
bk54	RX-RELATED NEURO-CLINICAL	
bk55	DEGREE METABOLIC	
bk56	RX-RELATED METABOLIC	
bk57	DEGREE COAGULATION	
bk58	RX-RELATED COAGULATION	
bk59	DEGREE OTHER 1	
bk60	TOXICITY-TYPE-OTHER 1	See below
bk61	RX-RELATED OTHER 1	
bk62	DEGREE OTHER 2	
bk63	TOXICITY-TYPE-OTHER 2	See below
bk64	RX-RELATED OTHER 2	
bk65	DEGREE OTHER 3	
bk66	TOXICITY-TYPE-OTHER 3	See below
bk67	RX-RELATED OTHER 3	
bk68	DEGREE OTHER 4	
bk69	TOXICITY-TYPE-OTHER 4	See below
bk70	RX-RELATED OTHER 4	
bk71	DEGREE OTHER 5	
bk72	TOXICITY-TYPE-OTHER 5	See below
bk73	RX-RELATED OTHER 5	
bk74	DEGREE OTHER 6	
bk75	TOXICITY-TYPE-OTHER 6	See below
bk76	RX-RELATED OTHER 6	
bk77	DEGREE OTHER 7	
bk78	TOXICITY-TYPE-OTHER 7	See below
bk79	RX-RELATED OTHER 7	
mainanal_flag	Main Analysis Flag	1=included in main analysis, 0 otherwise
toxanal_flag	Toxicity Analysis Flag	1=included in toxicity analysis, 0 otherwise

Toxicity Codes

Toxicity Type	Toxicity Code
taste alterations	6
Rhinitis	17
anorexia	20
dryness, mouth	21
epigastric distress	22
mucositis	32
insomnia	35
edema, leg	37
hotflashes	38
eye irritation	43
arthralgia	45
clotting disorders	46
conjunctivitis	51
myalgia/myopathy	52
dysphagia	54
vertigo	55
electrolyte imbalance	58
lacrimation	60
hoarseness	63
hyponatremia	66
pruritus	68
lightheadedness	69
pericardial effusion	74
embolus	75
thirst	77
nail changes	91
veno-occlusive dz (VOD)	96
all other toxicities	97
pain, other	111
impotence	112
cheilitis	117
hypocalcemia	128